

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of educational intervention based on Adult Learning Theory on oral health related quality of life among the elderly referred to dental clinic of Ahvaz Jundishapur University of Medical Sciences

Protocol summary

Study aim

The present study was conducted to determine the impact of educational intervention based on Adult Learning Theory on oral health related quality of life of the elderly.

Design

Clinical trials with intervention and control group (with parallel groups), blind and randomized using 6 blocks.

Settings and conduct

The place of study was all parts of dental faculty of Ahvaz Jundishapur University of Medical Sciences. Participants were randomly divided into experimental and control groups. After pre-test, educational programs were conducted for the interventional group. After one month, the questionnaire was again administered in both groups. Then, the results of pre-test and post-test were compared in each group separately.

Participants/Inclusion and exclusion criteria

Inclusion Criteria for this study were fluency in Persian, informed consent to participate in the study, good psychological and mental status, minimum score of the short cognitive performance test (>6) and literacy. Age less than 60 years old and having psychological disorders were non-admission conditions.

Intervention groups

Intervention group: The intervention included an individual training method using motivational interviewing, an e-learning method in the form of sending three short messages once a week and a group discussion method that was held in 1 one-hour session. Control group: control group received routine cares of dental clinic of Ahvaz Jundishapur University of Medical Sciences.

Main outcome variables

The overall score of oral health related quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120910010804N13**

Registration date: **2018-12-16, 1397/09/25**

Registration timing: **retrospective**

Last update: **2018-12-16, 1397/09/25**

Update count: **0**

Registration date

2018-12-16, 1397/09/25

Registrant information

Name

Marzieh Araban

Name of organization / entity

Tarbiat Modares University

Country

Iran (Islamic Republic of)

Phone

تهران

Email address

m.araban@modares.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-06-01, 1396/03/11

Expected recruitment end date

2017-07-21, 1396/04/30

Actual recruitment start date

2017-06-01, 1396/03/11

Actual recruitment end date

2017-07-21, 1396/04/30

Trial completion date

2017-11-30, 1396/09/09

Scientific title

The effect of educational intervention based on Adult Learning Theory on oral health related quality of life among the elderly referred to dental clinic of Ahvaz Jundishapur University of Medical Sciences

Public title

The effect of education on oral health related quality of life

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Being fluent in persian Informed consent to participate in the study Good psychological and mental status according to the clinician's diagnosis Minimum score of the short cognitive performance test (>6) Having at least ability to read and write

Exclusion criteria:

Receiving private sectors care

Age

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **92**

Actual sample size reached: **86**

Randomization (investigator's opinion)

Randomized

Randomization description

Allocating subjects to the study groups (intervention and control) was done random block using six blocks. This was done with WinPepi11.0 software (<http://www.brixtonhealth.com/pepi4windows.html>). This software generates random groups. In each block, 3 subjects were from the control group and 3 subjects were from the intervention group, which was arranged randomly. Finally, 16 blocks were used. The steps of using the software listed were as follows: ETCETERA, Randomization (Random allocation) , Balanced Randomization, Successive blocks.

Blinding (investigator's opinion)

Single blinded

Blinding description

In order to reduce the probability of information bias, the person evaluating the results (post-test) of the educational group was blinded to the participants' group assignment.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Ahvaz Jundishapur University of Medical Sciences, Esfand street, Golestan

City

Ahvaz

Province

Khouzestan

Postal code

61357-15794

Approval date

2017-06-17, 1396/03/27

Ethics committee reference number

IR.AJUMS.REC.1396.315

Health conditions studied

1

Description of health condition studied

Oral health related Quality of life in the elderly

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Oral health related quality of life in the elderly

Timepoint

Before the intervention and one month after the intervention is completed

Method of measurement

Standard questionnaire of Geriatric Oral Health Assessment Index

Secondary outcomes

1

Description

The Score of Effectiveness of Adult Learning Theory

Timepoint

Before the intervention and one month after the intervention

Method of measurement

Questionnaire consisted of 8 researcher-made questions

Intervention groups

1

Description

Intervention group: using face-to-face training methods in the form of 15 minute individual training using motivational interviewing methods, e-learning method (sending educational SMS) which included three short messages that were sent once a week for Individuals and the group discussion method was used as a 1-hour session.

Category

Lifestyle

2

Description

Control group: control group received routine cares of dental clinics of Ahvaz Jundishapur University of Medical Sciences.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Dentistry of Ahvaz University of Medical Sciences

Full name of responsible person

Elham Shokouhi

Street address

Ahvaz University of Medical Sciences, Esfand street, Golestan

City

Ahvaz

Province

Khuzestan

Postal code

61357-15794

Phone

+98 61 3333 3477

Email

e_shokouhi71@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr.Mohamad Badavi

Street address

Deputy of Research and Technology of Ahvaz University of Medical Sciences, Esfand street, Golestan

City

Ahvaz

Province

Khuzestan

Postal code

61357-15794

Phone

+98 61 3333 3477

Email

e_shokouhi71@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ahvaz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr.Marzieh Araban

Position

Assistant Professor of Ahvaz University of Medical Sciences

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

Street address

Ahvaz University of Medical Sciences, School of Public Health, Department of Health Education and Promotion

City

Ahvaz

Province

Khuzestan

Postal code

61357-15794

Phone

+98 61 3373 8612

Email

araban62@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Marzieh Araban

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

Street address

Medical University, Esfand St, Golestan

City

Ahvaz

Province

Khouzestan

Postal code

61357-15749

Phone

+98 61 3333 3477

Email

araban62@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr.Marzieh Araban

Position

Assistant Professor Ahvaz University of Medical Sciences

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

Street address

Ahvaz University of Medical Sciences, School of Public Health, Department of Health Education and Promotion

City

Ahvaz

Province

Khouzestan

Postal code

61357-15794

Phone

+98 61 3373 8612

Email

araban62@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data studied is sharing after unobtrusive.

When the data will become available and for how long

The access to information after publishing the results

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

The terms of sending the document will be explained to the requesting person.

From where data/document is obtainable

araban62@gmail.com e_shokouhi71@yahoo.com

What processes are involved for a request to access data/document

The request will be answered by the research team after the review.

Comments